

Regulatory Update: 7CFR330 Amendment - Implications for Biocontrol

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APHIS is in the process of revising 7CFR330, Federal Plant Pest Regulations; General; Plant Pests; Soil, and Quarry Products; Garbage Part 200-12, Movement of plant pests regulated, permits required. A draft proposed rule amending 7CFR330 is currently in USDA departmental review, and a draft Environmental Impact Statement has been completed. The draft proposed rule will implement Plant Protection Act 2000 requirements and codify permitting policy.

Permits are required to import, move interstate, transit the continental U.S., release into the environment, and possess plant pests, biological control organisms, and associated articles based on their direct and indirect effects on plant health. Some articles within the above-named categories will be proposed for exemption from permit requirement under 7CFR330. These will also include those regulated in other parts of 7CFR including 301, and those regulated by the Environmental Protection Agency.

Biological control organisms that are regulated by APHIS include:

- Invertebrate competitors and predators of invertebrate plant pests
- Invertebrate herbivores of noxious weeds
- Microbial pathogens of invertebrate plant pests and noxious weeds
- Microbial parasites of plant pathogens
- Other organisms designated by APHIS

Biological control organisms not regulated by APHIS' current permitting policy include:

- Bacteriophages
- Mycoviruses
- Viruses of insect plant pests
- Biological control organisms regulated by EPA

Three risk-based administrative categories for biological control organisms, Bio-C, Bio-B, and Bio-A, will be proposed. The highest risk category will include Bio-C organisms. Bio-C will include potential biocontrol organisms that have not yet been assessed by APHIS. Permits will be required for importation and interstate movement of Bio-C organisms, and no environmental release will be authorized. Bio-B organisms will include those for which APHIS has conducted an environmental assessment, concluding with a finding of no-significant impact, and environmental release has been authorized. Permits for importation and interstate movement will be required for Bio-B organisms.

Organisms in the Bio-A category are established throughout their ecological range within the continental United States for which it has been determined that subsequent environmental releases will not result in adverse impacts. Permits will be required for importation and interstate movement of Bio-A organisms from Hawaii and the territories, but not for interstate movement of these organisms within the continental U.S. Microbial organisms that are registered for use by EPA (Biopesticides) will be added to the Bio-A list as they are registered. Addition of other biocontrol organisms to the Bio-A and Bio-B categories will be implemented through a petition, review and Federal Register Notice process.

EPA regulates microbial biocontrol organisms based on “intent”; therefore, if there are no pesticidal claims associated with the intended use of the organism, EPA doesn’t regulate them. APHIS has broad authority to regulate organisms that have direct and indirect impacts on plant health. Initial field release of microbial biocontrol organisms involves EPA/USDA consultation. USDA evaluates the potential microbial biocontrol organism to determine its plant pest status. If the release is regulated by EPA under EUP then PPQ does not require a permit. Typically, APHIS regulates release of non-exempt organisms under 7CFR330 on acreages of 10 acres or less on land or 1 acre or less in water.

EPA and APHIS regulate microbial biocontrol agents as follows:

- ▶ APHIS oversight focuses primarily on microbial biocontrol agents originally isolated in foreign countries
- ▶ Microbial biocontrol agents isolated in USA typically do not require an APHIS permit for interstate movement or release in the environment (EPA will continue its current oversight of these microbes).
- ▶ Viruses of fungi, insects, and bacteria are exempt from APHIS oversight (EPA will continue its current oversight of these microbes).

If a foreign microbe is exotic to United States, and has not been reviewed by a competent authority, development of an Environmental Assessment in accordance with the requirements of the National Environmental Policy Act may be required. APHIS will NOT accept a regulatory decision of foreign country pertaining to the risk potential of an organism without its own internal review. APHIS believes that for some approved products there is sufficient scientific data that would greatly aid APHIS’ hazard identification process. Applicants could provide data obtained from the competent foreign authority, but additional data might be necessary. APHIS takes into consideration the following:

- the foreign isolate is similar or identical to the microbe present in U.S.,
- the foreign isolate is registered by a competent authority or is similar to an EPA-registered microbial pesticide.

If a wild type of pathogen release qualifies for NEPA Categorical Exclusion (CAT-EX) at a specific site, the release of an attenuated/avirulent strain at the same site would be also CAT-EX.

